No. 22-55173

IN THE

United States Court of Appeals for the Ninth Circuit

HOPE MEDICAL ENTERPRISES, INC.
D/B/A Hope Pharmaceuticals,

Plaintiff-Appellee,

v.

FAGRON COMPOUNDING SERVICES, LLC; JCB LABORATORIES, LLC; ANAZOAHEALTH CORPORATION; COAST QUALITY PHARMACY, LLC,

Defendants-Appellants.

On Appeal from the United States District Court for the Central District of California, No. 2:19-cv-07748-CAS-PLA

APPELLEE'S ANSWERING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellee Hope Medical Enterprises, Inc., d/b/a Hope Pharmaceuticals ("Hope"), is a privately owned corporation. It has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

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INTRODUCTION

Fagron asks this Court to eviscerate States' historic sovereign power to protect their citizens from untested, unapproved, and potentially unsafe drugs. Fagron makes and sells drugs that, all parties agree, have not received approval from the Food and Drug Administration or any State. But it sells those drugs in five States that, all parties also agree, prohibit the sale of unapproved drugs. So Hope sued Fagron under those five States' laws, claiming Fagron violated state consumer-protection laws by selling unapproved drugs prohibited by state drug-approval laws. And Hope proved its claims at trial: the district court found that since 2014, Fagron has violated those States' laws by selling a drug that has never received approval.

Fagron could not dispute that its drug had never received approval as required by the state laws that Hope invoked. Instead, Fagron's defense was that its drug was exempt from the FDA premarket approval requirement because, according to Fagron, it complied with the FDCA's provisions relating to drug compounding. And Fagron argued that it would conflict with federal law to enforce state laws requiring premarket approval if federal law did not require premarket approval. The legal

premise of Fagron's defense—that States lack authority to limit in-state sales of unapproved prescription drugs beyond the FDCA's limitations—is debatable. But because the factual premise of Fagron's defense is clearly incorrect—in truth, Fagron does *not* comply with the FDCA's compounding provisions and its drug is thus not exempt under federal law from the FDA premarket approval requirement—Hope was willing to accept Fagron's legal premise. Fagron argued its defense at trial, and the district court rejected it on the facts, making extensive findings that Fagron did not comply with the FDCA's compounding provisions.

On appeal, Fagron does not challenge *any* of the district court's findings. Fagron is thus reduced to arguing that federal law preempts Hope's claims for violations of state laws *even though Fagron does not comply with federal law*. According to Fagron, States are powerless to prohibit the in-state sale of unapproved drugs whose sale is equally prohibited by federal law. Fagron is wrong. The Supreme Court's and this Court's cases establish that the FDCA does not oust States from the traditional state-law fields of health, safety, and fair-competition regulation. True, only the United States can sue under the FDCA. But that does not mean States are disabled from enacting their own laws in

this field, such as the laws Hope sued under. And while the Supremacy Clause bars the enforcement of state laws that prohibit what federal law requires, conflict preemption without a conflict is an oxymoron. And here, based on the district court's unchallenged factual findings, Fagron's drugs were illegal to sell in the States at issue under both federal and state law. Because Hope's state-law claims parallel, rather than conflict with, federal law, there is no basis to hold them preempted.

Fagron's contrary argument rests entirely on a misreading of this Court's decision in *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040 (9th Cir. 2022), and a mischaracterization of Hope's claims. Fagron persistently pretends that Hope's state-law claims are identical to the claims this Court addressed in *Nexus*, in that they supposedly required Hope to prove that Fagron violated the FDCA, but that is false. It was false in the district court, it is false now, and Fagron cannot make it true through repetition. Whether Fagron violated the FDCA was relevant only to Fagron's *defense*: its argument that because it complied with the FDCA's requirements for compounding, States cannot prohibit the sale of its unapproved drug. But Hope did not need to disprove that defense as an element of its state-law

claims. So Hope's claims did not seek to enforce—and do not conflict with—the FDCA.

This Court should reject Fagron's radical preemption argument—which would create at least two circuit splits and all but eliminate States' longstanding authority to regulate drug sales and fair competition within their borders—and affirm the district court's judgment.

STATEMENT OF THE ISSUES

Whether the FDCA preempts state statutes that do not conflict with the FDCA's requirements or require proof of an FDCA violation.

STATEMENT OF THE CASE

A. Legal background

1. Fagron challenges States' power to regulate the in-state sale of drugs that have not been reviewed for safety or approved by any government body. At the founding, however, that power belonged *exclusively* to the States. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1906 Congress enacted its "first significant public health law," which "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs." *Id.* Even then, though, the federal government did not review or approve drugs before sale. *Id.* That changed in 1938 when

Congress passed the FDCA, which included a "provision for premarket approval of new drugs." *Id.*; *see* 1-ER-57.

The premarket approval requirement appears in section 505 of the FDCA. It provides that "[n]o person" may "introduce or deliver for introduction into interstate commerce any new drug" unless FDA has first "approv[ed]" an "application filed pursuant to [section 505]." 21 U.S.C. § 355(a). The premarket approval requirement "protect[s] the public health" by "assur[ing] the safety, effectiveness, and reliability of drugs." *Wyeth*, 555 U.S. at 567 (cleaned up).

2. The FDCA, like the 1906 Act before it, "supplemented" but did not override the "protection for consumers already provided by state regulation and common-law liability." *Id.* at 566. While expanding FDA's authority, Congress still "took care to preserve state law." *Id.* at 567. Far from occupying the field of drug regulation and ousting the States from that domain, Congress specified "that a provision of state law would only be invalidated upon a direct and positive conflict with the FDCA." *Id.* (cleaned up). And Congress has never enacted an express-preemption provision for state laws regulating prescription drugs. *Id.* at 574. State

and federal drug regulations have "coexiste[d]" for the FDCA's entire 85-year history. *Id.* at 581.

In particular, many States have "act[ed] within [their] historical purview to regulate health and safety" by "authorizing private suits to enjoin the intrastate distribution, sale, and marketing of an unapproved drug." U.S. Br. as Amicus Curiae at 16–17, *Athena Cosmetics, Inc. v. Allergan, Inc.*, 576 U.S. 1054 (2015) (No. 13-1379), 2015 WL 2457643 ("U.S. *Athena* Br."). As relevant here, California, Florida, Tennessee, South Carolina, and Connecticut (the "Five States") have all enacted laws prohibiting the in-state sale of a drug that has not received premarket approval from FDA under section 505 or from an appropriate state agency. 1-ER-77–83 ¶¶ 25, 32, 38, 44, 51; SER-35–43.

Specifically, California's Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" unless (1) "a new drug application has been approved for it . . . under Section 505 of the [FDCA]" or (2) the California Department of Health Services "has approved a new drug or device application for that drug." Cal. Health & Safety Code § 111550(a)–(b). Florida prohibits the in-state sale of "any new drug unless an approved application has become effective under [section] 505

of the [FDCA] or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services." Fla. Stat. § 499.023. Tennessee prohibits the sale of "any new drug unless an application with respect to that drug has become effective under § 505 of the [FDCA]." Tenn. Code § 53-1-110. South Carolina prohibits the sale of "any new drug" unless the state's Commissioner of Health and Environmental Control approves the drug or "an application with respect thereto has been approved . . . under § 505 of the [FDCA]." S.C. Code § 39-23-70(a). And Connecticut prohibits the sale of "any new drug unless . . . an application with respect thereto has been approved under Section [505] of the [FDCA]." Conn. Gen. Stat. § 21a-110.

The Five States have also enacted consumer-protection laws that allow private litigants to sue based on violations of other state laws. *See* Cal. Bus. & Prof. Code § 17200; Fla. Stat. §§ 501.203, 501.204, 501.211; Tenn. Code § 47-18-104; S.C. Code §§ 39-5-20, 39-23-70; *Ulbrich v. Groth*, 78 A.3d 76, 100 (Conn. 2013). All Five States' consumer-protection laws authorize lawsuits to enforce those States' drug-approval laws. 1-ER-77–82 ¶¶ 24, 32, 38, 44, 50–51.

3. Traditionally, "compounding" referred to a pharmacist's "combin[ing], mix[ing], or alter[ing] ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). If not appropriately confined, however, "compounding" can become a fig leaf for the large-scale manufacturing of unapproved drugs—as it did for Fagron. Until the early 1990s, "FDA generally left regulation of compounding to the States." *Id.* at 362. But "FDA eventually became concerned . . . that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Id.* And in 2012, a "catastrophe" involving compounding—"a mass outbreak of deadly meningitis caused by contaminated compounded drugs"—led Congress to enact the current FDCA provisions relating to compounding. *Nexus*, 48 F.4th at 1043.

Those provisions—sections 503A and 503B of the FDCA—impose strict requirements for different kinds of compounding that, when satisfied, exempt a drug from premarket approval under section 505.

21 U.S.C. §§ 353a(a), 353b(a); *see* 1-ER-58–59 ¶ 17.[1] As relevant to Fagron's defense, section 503B governs "outsourcing facilities," which (unlike traditional compounders) may produce "large quantities" of standardized drugs, but only under limited circumstances justifying reliance on such an unapproved drug. 1-ER-62 ¶¶ 27–28.

Among other restrictions, "[s]ection 503B specifically limits the types of drugs that can be compounded at outsourcing facilities" using bulk drug substances (*i.e.*, a drum of the active ingredient): either (1) the "bulk drug substance" must "appear[] on a list established by [FDA] identifying bulk drug substances for which there is a clinical need" for use by outsourcing facilities (known as the "bulks list"); or (2) the "drug compounded from such bulk drug substance" must "appear[] on the drug shortage list" created by FDA. 21 U.S.C. § 353b(a)(2); 1-ER-62 ¶ 29 (cleaned up). A 503B facility cannot compound drugs "using bulk drug substances" unless it satisfies one of these two conditions. 21 U.S.C.

[1] Contrary to Fagron's claim that only FDA can regulate compounding, Br. 30, "[m]any States specifically regulate compounding practices as part of their regulation of pharmacies." *W. States Med. Ctr.*, 535 U.S. at 361. California, for instance, independently regulates compounding, but Fagron has never claimed to satisfy California's (or any other State's) compounding requirements. *E.g.*, Cal. Code Regs. § 1735.2.

§ 353b(a)(2); *see Azurity Pharms., Inc. v. Edge Pharma, LLC*, 45 F.4th 479, 501 (1st Cir. 2022); *Athenex Inc. v. Azar*, 397 F. Supp. 3d 56, 60 (D.D.C. 2019). In this way, outsourcing facilities fill gaps in commercially available, FDA-approved drugs, but do not displace FDA-approved drugs. *See* FDA, *Guidance for Industry: Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act* 4–6 (Mar. 2019), https://www.fda.gov/media/121315/download ("*503B Bulk Drug Substance Guidance*").

To further ensure that outsourcing facilities' unapproved drugs do not displace FDA-approved drugs, section 503B also forbids the compounding of drugs that are "essentially a copy" of approved drugs. 21 U.S.C. § 353b(a); 1-ER-62–63 ¶ 30. Although Fagron elides this fact (*see* Br. 27–28), Section 503B contains two distinct "essentially a copy" provisions. The first applies to compounded drugs made using a finished, FDA-"approved drug" as the starting point. 21 U.S.C. § 353b(d)(2)(A). This is called "sterile-to-sterile" compounding. *Athenex*, 397 F. Supp. 3d at 60. The other "essentially a copy" provision applies to compounded drugs that are made using "bulk drug substances," rather than starting from a finished, FDA-approved drug product. 21 U.S.C. § 353b(d)(2)(B).

This Court has already recognized that only "bulk drug compounding"—not sterile-to-sterile compounding—is at issue in this case. *Hope Med. Enters. v. Fagron Compounding Servs.*, 2021 WL 5860886, at *1 (9th Cir. Dec. 10, 2021); *see* SER-33 ¶ 13.

Compounding from bulk drug substances poses greater threats to patients and the integrity of the FDA approval process than sterile-to-sterile compounding, so Congress imposed greater restrictions on it, including a broader "essentially a copy" prohibition. FDA, *503B Bulk Drug Substance Guidance* 4–6. A compounded drug is "essentially a copy" of an FDA-approved drug if it contains "a bulk drug substance that is a component of an approved drug." 21 U.S.C. § 353b(d)(2)(B). And a 503B facility may compound a drug that is "essentially a copy" of an approved drug only if a "prescribing practitioner" provides a statement attesting that the compounded drug's "change" to the copied drug "produces for an individual patient a clinical difference." *Id.* These attestations are known as "clinical difference statements." 1-ER-63 ¶ 31.

Under FDA's guidance for bulk-drug-substance compounding, a clinical difference statement must "be noted on the prescription or order . . . for the compounded drug," "specify the change between the

compounded drug and the comparable approved drug," and "indicate that the compounded drug will be administered or dispensed only to a patient for whom the change produces a clinical difference, as determined by the prescribing practitioner for that patient." 1-ER-63 ¶ 31 (cleaned up).

4. Although the FDCA contains no preemption provision for state laws regulating prescription drugs, it does limit the class of plaintiffs who have standing to enforce its requirements. The FDCA's standing provision states that all "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a).

That provision makes clear that the FDCA does not create a private right of action that would enable private plaintiffs to directly enforce the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). But the FDCA's standing provision does not say that States are prohibited from enacting their own laws that "borrow" or "parallel" the FDCA's requirements, and this Court has held that it does not bar such state-law claims. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc); *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040–41 (9th Cir. 2015). Courts have accordingly held that the FDCA does not

categorically preempt state drug-approval laws like California's Sherman Law. *E.g.*, *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354–56 (Fed. Cir. 2013), *cert. denied*, 576 U.S. 1054 (2015); *Farm Raised Salmon Cases*, 175 P.3d 1070, 1181–84 (Cal. 2008), *cert. denied sub nom. Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009). The United States agrees, as the Solicitor General explained in briefs filed in both of those cases in response to the Supreme Court's invitation. U.S. *Athena* Br. 8–17; U.S. Br. as Amicus Curiae at 8–20, *Albertson's*, 555 U.S. 1097 (No. 07-1327), 2008 WL 5151069 (U.S. *Albertson's* Br.).

In a different context, this Court recently held the FDCA barred a suit where a private plaintiff contended that the defendant's drug violated the Sherman Law and other state drug-approval laws *because* it violated the FDCA's "essentially a copy" provision for sterile-to-sterile compounding. *Nexus*, 48 F.4th at 1044. The *Nexus* plaintiff's claims, in other words, required proof that the defendant's drug *both* lacked FDA approval *and* violated section 503B of the FDCA. *Id.* Because "a necessary element" of the plaintiff's claims was a violation of the FDCA's "essentially a copy" provision for sterile-to-sterile compounding, the Court held that the plaintiff was improperly trying to enforce the FDCA.

Id. at 1048. The Court also held that because the plaintiff's claims "depend[ed] on a determination of whether" the defendant's drug was "'essentially a copy' of" the plaintiff's drug under section 503B's provision for sterile-to-sterile compounding, its claims conflicted with FDA's authority to interpret that provision. *Id.* at 1050.

B. Factual background

This appeal comes to this Court after a bench trial following which the district court made numerous detailed findings of fact. 1-ER-52–99. Fagron does not ask this Court to reject any of those findings. Instead, it ignores them, presenting a fictional narrative that the district court rejected in almost every particular. What follows is the truth.

1. Fagron sells an unapproved copy of Hope's FDA-approved Sodium Thiosulfate Injection.

Hope and Fagron are competitors in the marketplace for drugs containing sodium thiosulfate. 1-ER-53 ¶ 2. Dialysis providers buy those drugs for the off-label use of treating calciphylaxis, a condition suffered by some dialysis patients. 1-ER-64 ¶ 39; 1-ER-104. The district court found Hope and Fagron were the only companies that sell sodium thiosulfate drugs to dialysis companies. 1-ER-78 ¶ 28, 1-ER-88 ¶ 67.

Hope sells "Sodium Thiosulfate Injection," the only FDA-approved drug with sodium thiosulfate as an active pharmaceutical ingredient at all relevant times. 1-ER-63 ¶¶ 32–33. In 2012, Hope received FDA approval to sell its Sodium Thiosulfate Injection to treat acute cyanide poisoning. *Id.* Hope sells its Sodium Thiosulfate Injection throughout the country, including unsolicited sales to dialysis companies in the Five States. 1-ER-64–65 ¶ 40.

Fagron mass-produced and sold an injectable sodium thiosulfate drug with the same concentration of sodium thiosulfate as Hope's Sodium Thiosulfate Injection. 1-ER-63–64 ¶ 34, 1-ER-67 ¶ 53. It is undisputed that Fagron's drug has not received premarket approval from FDA or any state agency. 1-ER-64 ¶ 35, 1-ER-74 ¶ 10. Fagron claimed to be exempt from the FDCA's premarket approval requirement because it "compounds" its drug through affiliates. 1-ER-64 ¶ 35. At the relevant time, Fagron's affiliate AnazaoHealth owned and operated a 503A pharmacy in Florida. 1-ER-64 ¶ 38. Fagron Compounding Services and Fagron's affiliate JCB Laboratories own and operate 503B facilities in Kansas. 1-ER-64 ¶ 37. Fagron sold its unapproved sodium thiosulfate

drug throughout the country, including in the Five States. 1-ER-65 ¶¶ 41–42.

Although Fagron claims its unapproved drug serves a patient need because it does not contain potassium, that is a smokescreen. Br. 7. Fagron began selling its drug a decade ago, but before 2017 it never touted the drug's lack of potassium as a relevant difference from Hope's Sodium Thiosulfate Injection. What happened in 2017 is that Fagron "became concerned" that its unapproved drug was illegal. 1-ER-68 ¶ 61. So it "explored several approaches to justify selling [its] sodium thiosulfate compounded drug, including changing [its] sodium thiosulfate's formulation to be 10 percent different from Hope's drug; selling [its] drug in a 100 mL vial instead of the 50mL used by Hope, and asserting that Hope's drug might be dangerous because Hope offered its sodium thiosulfate drug in a package that also contained sodium nitrite." 1-ER-68–69 ¶ 61. After rejecting those ideas, Fagron "decided that [it] could use the presence of potassium in Hope's product to justify the compounding and sale of defendants' drug to dialysis clinics." 1-ER-69 ¶ 62. At trial, however, Fagron introduced no evidence that "any prescribing practitioner" has ever "request[ed] a potassium-free version of sodium

thiosulfate." *Id.*[2] And FDA rejected as "inaccurate" Fagron's claim that "the potassium level of [Hope's] product is too high." 87 Fed. Reg. 4240, 4249 (Jan. 27, 2022) (2-ER-216). As FDA found, there is no evidence that "[t]he amount of potassium being administered with the approved sodium thiosulfate product . . . makes it medically unsuitable to treat patients with calciphylaxis." *Id.*; 1-ER-68 ¶ 60.

The truth is that Fagron's customers bought its unapproved drug instead of Hope's approved Sodium Thiosulfate Injection purely because Fagron—not having incurred the expense of seeking and receiving premarket approval—could sell its drug at lower prices. *See* 1-ER-65–66 ¶¶ 43–52, 1-ER-78 ¶ 27, 1-ER-80–81 ¶¶ 40, 46, 1-ER-83 ¶ 53.

2. Fagron's unapproved drug is not exempt from premarket approval.

As explained in more detail below, Hope's state-law claims against Fagron depend on nothing more than proof that—as Fagron concedes—its drug has not received premarket approval under FDCA section 505 or

[2] The supposed evidence Fagron cites, Br. 7; 2-ER-360–76, comprises two self-serving letters from "business executives," not "prescribing practitioner[s]" who treat dialysis patients, 1-ER-69 ¶ 63. These executives stated their "professed need for a potassium-free sodium thiosulfate injection" only after "discussions with defendants." *Id.*

from a state agency. But as a defense to those claims, Fagron argued its drug was exempt from premarket approval. *E.g.*, SER-28, 102–05, SER-118 ¶ 1. After a trial, the district court found that Fagron's drug was *not* exempt from premarket approval. Fagron does not ask this Court to disturb any of the district court's findings. Yet Fagron blithely tells the Court that its "compounded drug is exempt from pre-market approval," as if there had not been a trial—that Fagron lost—about that precise contention. Br. 30. For two reasons, it is crystal clear that Fagron's drug is not exempt from the FDA premarket approval requirement—and thus that Fagron's argument that the FDCA preempts state-law drug-approval requirements when a drug is exempt from premarket approval under the FDCA's compounding provisions is beside the point.

First, Fagron's drug is not exempt from premarket approval because (a) sodium thiosulfate has never appeared on FDA's "bulks list" of bulk drug substances for which there is a clinical need for use by 503B facilities, and (b) Hope's Sodium Thiosulfate Injection has never appeared on FDA's drug shortage list. Fagron claims it could use bulk sodium thiosulfate between October 30, 2019, and July 31, 2020, while sodium thiosulfate was on FDA's "list of Category 1 substances that

[were] currently under evaluation" for the bulks list. 1-ER-68 ¶ 58 (quotation marks omitted). Before October 30, 2019, however, sodium thiosulfate did not appear on the bulks list or the "Category 1" list. 1-ER-68 ¶ 59. Fagron nonetheless used bulk sodium thiosulfate to make its drug for years before that date, when it was not even arguably "exempted from the premarket approval requirement." 1-ER-65 ¶¶ 42–44, 1-ER-76 ¶ 19.[3]

And FDA has now conclusively decided that sodium thiosulfate will not appear on the bulks list. In July 2020, "FDA published a Notice in the Federal Register, proposing that sodium thiosulfate not be included on the 503B bulks list because it 'f[ound] no basis to conclude that there is a clinical need for outsourcing facilities to compound drug products using . . . sodium thiosulfate.'" 1-ER-68 ¶ 60 (quoting 85 Fed. Reg. 46,126,

[3] FDA's enforcement policy is generally not to take action against 503B facilities for using a bulk drug substance nominated for the bulks list while that substance is on FDA's "Category 1" list while FDA evaluates whether a "clinical need" exists for its use by 503B facilities. 1-ER-68 ¶¶ 58, 60. While it remains unlawful to use a bulk drug substance on the "Category 1" list—section 503B requires the bulk drug substance be on the list of substances for which FDA has found a clinical need, not merely that it be under consideration for inclusion, 21 U.S.C. § 353b(a)(2)(A)(i)—the Court need not consider the relationship between FDA's "Category 1" enforcement policy and section 503B or Hope's state-law claims given that Fagron undisputedly used bulk sodium thiosulfate to make its unapproved drug for years when it was not on the Category 1 list.

46,141 (July 31, 2020)). FDA finalized that decision in January 2022, finding "no clinical need for compounding from the bulk drug substance sodium thiosulfate." 87 Fed. Reg. at 4249–50 (2-ER-216–17). FDA rejected Fagron's argument that patients needed its drug as an alternative to Hope's drug because the potassium in Hope's drug could pose a threat to patients. *Id.* at 4249 (2-ER-216). FDA thus decided not to place bulk sodium thiosulfate on the bulks list and removed it from the Category 1 list. *Id.* Fagron did not challenge FDA's final "no clinical need" decision and concedes it can no longer sell its unapproved drug under federal law. Br. 19, 31; 1-ER-39.

Second, Fagron's drug is not exempt from premarket approval because it is "essentially a copy" of Hope's Sodium Thiosulfate Injection. It is undisputed that "a component" of Fagron's drug is bulk sodium thiosulfate, which is also "a component of an approved drug," namely Hope's Sodium Thiosulfate Injection. 21 U.S.C. § 353b(d)(2)(B); *see* 1-ER-74 ¶ 11. Yet Fagron sold its unapproved drug without the necessary "clinical difference" statements. 21 U.S.C. § 353b(d)(2)(B); 1-ER-69–71 ¶¶ 64–73, 1-ER-74–76 ¶¶ 12–18. Throughout the relevant period, Fagron sold its drug to one of its two corporate dialysis customers that operates

thousands of clinics nationwide, without *ever* receiving a "clinical difference statement signed by a prescribing practitioner or a person authorized to act on a practitioner's behalf." 1-ER-69 ¶ 64, 1-ER-75 ¶ 15. For sales to its other corporate dialysis customer, Fagron either (1) received no clinical difference statement at all, (2) received statements that were not "signed by a prescribing practitioner or a person authorized to act on a practitioner's behalf," or (3) received "blanket attestation forms" unrelated to any actual patient. 1-ER-69–71 ¶¶ 65–73, 1-ER-75 ¶ 14.[4]

C. Procedural history

1. In this lawsuit, Hope claimed Fagron violated the Five States' unfair-competition laws by selling unapproved drugs in violation of each State's drug-approval law. 3-ER-652–57 ¶¶ 97–137. Hope's complaint alleged that all Five States prohibit the sale of new drugs absent "an

[4] Fagron's drug is also "essentially a copy" of Hope's Sodium Thiosulfate Injection under section 503A's somewhat different definition of that term, and Fagron's 503A pharmacy did not provide the necessary "significant difference" statements. 1-ER-67 ¶¶ 53–56, 1-ER-72–74 ¶¶ 2–9; 21 U.S.C. § 353a(b)(1)(d), (b)(2). However, Fagron's 503A pharmacy stopped selling its sodium thiosulfate drug before the conclusion of this litigation, so the district court's permanent injunction does not apply to that pharmacy. It applies only to Fagron's 503B facilities. 1-ER-2–5, 99.

application approved by FDA under section 505 of the FDCA." 3-ER-638 ¶ 45. It alleged Fagron violated those laws "because [it] ha[s] not obtained the approval of FDA (or any other relevant regulatory authority)" for its "sodium thiosulfate drugs." 3-ER-640 ¶ 55.

To head off Fagron's defense that it is "exempt" from state "drug-approval requirements," Hope also explained that Fagron did not satisfy the FDCA's compounding requirements. 3-ER-634 ¶ 21, 3-ER-640–46. But Hope's claims themselves are based solely on Fagron's sale of drugs that have not received premarket approval. 3-ER-640 ¶ 55. Hope's claims do not also require proof that Fagron violated the FDCA.

2. Hope moved for a preliminary injunction in June 2020. Dkt. 105. Fagron opposed the motion by arguing, among other defenses, that the FDCA preempted Hope's claims. Dkt. 113. The district court granted Hope's motion. 1-ER-180–81. Fagron did not appeal.

Around five months later, Fagron moved the district court to reconsider the preliminary injunction on the basis of preemption. 2-ER-307–12. Fagron cited supposed "new facts and law" that it claimed "warrant[ed] reconsideration." 2-ER-311. First was the district court's decision in the *Nexus* cases, dismissing those cases on preemption

grounds. 2-ER-307–12. Second was a declaration submitted in the *Nexus* cases by an FDA employee named Maria Gozun. 2-ER-311–12. Because the plaintiff in *Nexus* claimed the defendant violated the FDCA's "essentially a copy" provision for sterile-to-sterile compounding, Ms. Gozun addressed only "the 'essentially a copy' provisions . . . with respect to outsourcing facilities that compound drug products using FDA-approved drug products—*rather than bulk drug substances*—as a starting point." SER-115 ¶ 8 (emphasis added); *see Nexus*, 48 F.4th at 1044. She noted FDA planned to issue a "revision to its guidance" on sterile-to-sterile compounding. SER-115–16 ¶ 9.

Ms. Gozun's declaration did not address compounding that, unlike sterile-to-sterile compounding, "start[s] with . . . a bulk drug substance." *Id.* Indeed, she later stated in another declaration that, unlike with sterile-to-sterile compounding, FDA had no plans to revise "its guidance for applying the 503B 'essentially a copy' provision[] when outsourcing facilities compound drugs using bulk drug substances as a starting point." 2-ER-271. FDA's guidance for applying the "essentially a copy" prohibition to bulk-drug-substance compounding, according to Ms. Gozun, is final. *Hope*, 2021 WL 5860886, at *1.

3. The district court denied Fagron's motion for reconsideration, and Fagron appealed. This Court dismissed the appeal for lack of jurisdiction. *Hope*, 2021 WL 5860886, at *1–2.

This Court held it lacked jurisdiction because Fagron's motion for reconsideration was not "based on new circumstances that arose after the district court granted the preliminary injunction." *Id.* at *1. The *Nexus* decision was not a "relevant 'new circumstance'" because it was "not binding on the district judge." *Id.* The "Gozun declaration" also did not "constitute 'new circumstances'" because it "addresse[d] a type of drug compounding"—that is, sterile-to-sterile compounding—"that is not at issue in this case. And the part of the declaration addressing bulk drug compounding facilities, like those operated by Fagron, state[d] that the FDA has not changed and is not planning to change its regulations concerning such facilities." *Id.*

Fagron did not seek further review of this Court's decision. It now constitutes law of the case. *See Rocky Mountain Farmers Union v. Corey*, 913 F.3d 940, 951 (9th Cir. 2019).

4. Shortly before trial, the parties jointly submitted a proposed Pretrial Conference Order containing various stipulated facts. SER-30.

The parties stipulated, for example, that Fagron "ha[s] not applied for FDA approval of [its] compounded sodium thiosulfate drug." SER-32 ¶ 5. The parties also stipulated that "sodium thiosulfate" is a "component" of both Hope's Sodium Thiosulfate Injection and Fagron's unapproved drug. SER-33 ¶¶ 10–11. Finally, the parties stipulated that this case does not involve sterile-to-sterile compounding because Fagron "ha[s] always used bulk sodium thiosulfate and ha[s] never compounded [its] sodium thiosulfate drug product from a finished drug product." SER-33 ¶ 13.

The proposed pretrial order also set forth the elements of Hope's claims. The parties agreed that Hope brought claims only under state law, and they agreed that all Five States prohibit the sale of drugs that have not received premarket approval under FDCA section 505. SER-35–43. Neither party asserted that a violation of the FDCA was an element of any of Hope's claims. *Id.* To the contrary, Hope explained that its "claims are based solely on [Fagron's] sale of drugs that have not received premarket approval." SER-44. Hope then acknowledged and addressed Fagron's "defense" that it is "exempt from state drug-approval laws because [it] 'compound[s]' [its] drugs consistent with federal law." *Id.*

Fagron did not disagree with that description of Hope's claims. To the contrary, Fagron's Trial Brief acknowledged that Hope's claim is "that any sales of drugs not approved by the FDA violate[] the various state [drug-approval] laws." SER-29. As Fagron admitted, Hope argues that compounded drugs are not "approved by the FDA" irrespective of "the FDA regulatory scheme for compounding drugs." *Id.*

5. The district court held a bench trial in the summer of 2021. 1-ER-52. The court then issued a detailed decision, which concluded that Fagron's sale of its unapproved sodium thiosulfate drug violated the Five States' consumer-protection and drug-approval laws. 1-ER-77–83. In particular, the court found that Fagron's drug violated the States' drug-approval laws because it has not "been approved by the FDA under FDCA Section 505." 1-ER-77 ¶ 25 (cleaned up); *see* 1-ER-78–83 ¶¶ 32, 38, 44, 51.

Because Fagron rested its entire case on its defense that its drug was exempt from premarket approval under federal law, the district court considered and rejected that defense. It found that "[b]ulk sodium thiosulfate has never appeared on the 503B bulks list, and Hope's Sodium Thiosulfate Injection has not appeared on the drug shortage list." 1-ER-67 ¶ 57. It also found that Fagron's unapproved drug is "essentially a

copy" of Hope's Sodium Thiosulfate Injection under section 503B's provision for bulk-drug-substance compounding. 1-ER-74 ¶ 11. Fagron, however, sold its drug without receiving the necessary "clinical difference" statements. 1-ER-68–71 ¶¶ 61–73, 1-ER-74–76 ¶¶ 12–18. As a result, the district court found that Fagron's drug was not "exempt[]" from premarket approval under the FDCA. *E.g.*, 1-ER-73–74 ¶¶ 7–8, 1-ER-76 ¶ 19, 1-ER-78–83 ¶¶ 26, 33, 39, 45, 52. At no point, however, did the court hold that Fagron's FDCA violations were an element of Hope's state-law claims. To the contrary, the court found Fagron violated state drug-approval laws for the simple reason that its drug has not received approval under section 505. 1-ER-77 ¶ 25, 1-ER-80–83 ¶¶ 38, 44, 51.

The district court enjoined Fagron from "dispensing or distributing" its unapproved "sodium thiosulfate product from a Section 503B outsourcing facility into" the Five States unless Fagron receives a "clinical difference" statement. 1-ER-42.

5. After the district court issued its decision, FDA made its final determination not to place bulk sodium thiosulfate on the 503B bulks list. 87 Fed. Reg. at 4249–50 (2-ER-216–17). Because that decision establishes that no injectable drug containing bulk sodium thiosulfate can be exempt

from premarket approval under section 503B, Hope moved the district court to amend its judgment accordingly. 2-ER-183. Although Fagron opposed Hope's motion on meritless procedural grounds, Fagron "concede[d]" that FDA's decision prevented it from "compound[ing] sodium thiosulfate" without premarket approval. 1-ER-39. It concedes the same to this Court. Br. 19, 31.

The district court amended its injunction. 1-ER-10–11. It enjoined Fagron from "distributing" its unapproved drug into the Five States unless (1) "bulk sodium thiosulfate appears on" FDA's bulks list, (2) "the drug compounded by [Fagron] from bulk sodium thiosulfate appears on FDA's 'drug shortage' list," or (3) "bulk sodium thiosulfate appears on FDA's 'Category 1' list." 1-ER-3. The court also preserved its earlier injunction requiring "clinical difference" statements. 1-ER-3–4. While the injunction enforces the Five States' consumer-protection and drug-approval laws, it thus does so only in circumstances where state law parallels federal law—where Fagron's drug does not comply with section 503B and is not exempt from premarket approval under federal law. In this way, and consistent with Hope's limitation of the relief it sought, the court's decision takes off the table Fagron's contention that it would

conflict with federal law to enforce these state drug-approval laws in circumstances where federal law does not require FDA approval.

SUMMARY OF ARGUMENT

The FDCA's standing provision, 21 U.S.C. § 337(a), says that only the United States can sue to enforce the FDCA. It does *not* say that States are powerless to enact their own laws relating to drug safety and fair competition. Nor does the FDCA contain an express preemption provision relating to prescription drugs. States thus remain free to enact laws that parallel, rather than conflict with, the FDCA if States view such laws as appropriate to protect health, safety, or fair competition for their citizens.

The Five States' laws at issue prohibit the in-state sale of unapproved drugs. The FDCA generally also prohibits the sale of unapproved drugs. Fagron would like to argue that it conflicts with federal law to enforce state drug-approval laws where federal law exempts a drug from FDA premarket approval. But that question is irrelevant, because Fagron's drug does not comply with the FDCA's conditions for exempting compounded drugs from premarket approval.

So Fagron is left to argue that it somehow conflicts with federal law to enforce state drug-approval laws where federal law *also* requires

approval and where selling the unapproved drug violates federal and state law alike. But you can't have conflict preemption without a conflict, so Fagron is in reality arguing for *field* preemption—that when Congress provided that only the United States could sue to enforce the FDCA, what it meant was that States could no longer enact their own laws relating to drug safety or fair competition, full stop, even where state law parallels or incorporates federal law rather than conflicting with it. That position is outlandish. Health, safety, and competition are traditional areas of state authority, and binding precedent from the Supreme Court as well as this Court refutes the notion that Congress ousted the States from those fields and entrusted them entirely to FDA.

Fagron argues otherwise based solely on this Court's decision in *Nexus*, but that decision does not govern this case. *Nexus* held that the plaintiff's state-law claims were barred for two reasons. First, the Court found that the plaintiff sought to enforce the FDCA's "essentially a copy" provision for sterile-to-sterile compounding as a "necessary element" of its state-law claims. 48 F.4th at 1044, 1048. The Court held this conflicted with the FDCA's standing provision. *Id.* Second, and relatedly, the Court held the plaintiff's claims "depend[ed] on a determination of whether" the

defendant's drug was "'essentially a copy' of" the plaintiff's drug under the FDCA's "'essentially a copy' provision" for sterile-to-sterile compounding, which conflicted with FDA's authority to interpret that provision. *Id.* at 1050.

Neither of these rationales applies to Hope's claims. Contrary to Fagron's repeated assertions otherwise, Hope's state-law claims did not require it to prove that Fagron violated the FDCA. All Hope needed to prove under state law is the basic fact—undisputed here—that Fagron has not received premarket approval for its drug. Hope's claims do not require proof that Fagron also violated the FDCA's compounding provisions.

Nor do Hope's claims conflict with FDA's authority to interpret the FDCA. They required only proof that Fagron's drug has not received premarket approval, which is a simple (and undisputed) question of historical fact that does not require any interpretation of the FDCA. That aside, *Nexus* was decided on a motion to dismiss, while this case comes to the Court after a trial at which the district court found that Fagron's unapproved drug is not exempt from premarket approval. And Fagron's drug is not exempt for reasons that *Nexus* did not and could not consider. Fagron's drug is made from bulk sodium thiosulfate, but sodium

thiosulfate does not appear on FDA's 503B bulks list (or even FDA's interim "Category 1" list) and Hope's drug does not appear on FDA's drug shortage list. As a result, Fagron cannot produce its drug consistent with section 503B—as Fagron now concedes. No interpretation of the FDCA is needed to reach this conclusion either: you just have to look at the lists. In addition, Fagron did not comply with the FDCA's "essentially a copy" provision for *bulk-drug-substance compounding*. That is a different "essentially a copy" provision than the one at issue in *Nexus*, and applying it here involves no question of interpretation that could conflict with FDA's authority—especially given that FDA's guidance as to this provision is settled, in contrast to the unsettled state of guidance for the sterile-to-sterile compounding at issue in *Nexus*.

For all these reasons, the FDCA—even as interpreted in *Nexus*—does not preempt Hope's claims. If this Court adopted Fagron's radical interpretation of *Nexus*—barring state-law claims enforcing state drug-approval laws despite the district court's unchallenged factual findings that Fagron's drug needed approval under federal law too—it would conflict with Supreme Court precedent, en banc and panel opinions from this Court, decisions from other federal courts of appeals and the

California Supreme Court, and the United States' own considered views on FDCA preemption. Those conflicts would demand intervention and correction by the en banc Court. Thankfully, the Court need not and should not interpret *Nexus* to require that result. It should affirm the district court's judgment.

STANDARD OF REVIEW

Fagron appeals a final judgment entered after trial. Because Fagron does not challenge any of the district court's factual findings, the Court should treat those findings as correct. *United States v. Grey*, 959 F.3d 1166, 1169 n.1 (9th Cir. 2020). The Court reviews *de novo* the district court's "conclusions of law." *Secular Orgs. for Sobriety, Inc. v. Ullrich,* 213 F.3d 1125, 1129 (9th Cir. 2000).

ARGUMENT

I. The FDCA's standing provision does not bar Hope's claims because Hope sued under state law to enforce state law.

Fagron's argument that the FDCA's standing provision, section 337(a), bars Hope's claims depends entirely on its persistent mischaracterization of Hope's claims as being "wholly based on alleged violations of the [FDCA]." *E.g.*, Br. 1. In truth, Hope's claims invoke state-law causes of action provided by the Five States' consumer-protection

laws to sue for violations of those States' drug-approval laws. Those state laws, moreover, did not require Hope to prove any violation of the FDCA. So Fagron, to prevail, must show that Congress stripped the Five States of authority to enact those consumer-protection and drug-approval laws. Fagron cannot do so: section 337(a) makes clear that only the United States can sue to enforce the FDCA, but it does not disable States from enacting their own laws that parallel, rather than conflict with, federal law.

A. The FDCA's standing provision does not bar States from enacting laws that parallel the FDCA.

Federal law can preempt state law in three ways. The first, "*express* preemption," exists when a federal statute contains an "express preemption provision" displacing certain categories of state law. *Arizona v. United States*, 567 U.S. 387, 399 (2012). The FDCA does not expressly preempt state laws related to prescription drugs. *Wyeth*, 555 U.S. at 574.

The second form of preemption, "*field* preemption," prevents states "from regulating conduct in a field that Congress . . . has determined must be regulated by its exclusive governance." *Arizona*, 567 U.S. at 399, 401 (emphasis added). Fagron does not openly argue the FDCA occupies the field of drug regulation, and such a contention would be a non-starter. *Stengel*, 704 F.3d at 1230–31 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470,

486–89 (1996)); *see Wyeth*, 555 U.S. at 575 ("Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.").

That leaves "*conflict* preemption," under which state laws that "conflict[] with federal law" are invalid under the Supremacy Clause, even absent a federal statutory provision expressly preempting them. *In re Volkswagen "Clean Diesel" Mktg., Sales Practices, & Prods. Liab. Litig.*, 959 F.3d 1201, 1212 (9th Cir. 2020) (emphasis added) (cleaned up). The distinctive feature of conflict preemption is, of course, the requirement of a conflict, and this Court's precedent makes clear that conflicts are not lightly found, especially in areas of traditional state authority.

A classic case for conflict preemption is where it is impossible to comply with federal and state law at the same time. *Id.* Fagron makes no such argument. Beyond such "impossibil[ity]" situations, conflict preemption—then often known as "obstacle preemption"—exists "in only a small number of cases." *Id.* (cleaned up). First, it may exist when a state law "directly interfere[s] with the operation of [a] federal program," such as "exercising foreign affairs powers, sanctioning fraud on a federal agency, and regulating maritime vessels." *Id.* (cleaned up). Second, it

may exist when "a federal enactment clearly struck a particular balance of interests that would be disturbed or impeded by state regulation." *Id.* "Absent such circumstances, the Supreme Court has frequently rejected claims of obstacle preemption." *Id.* at 1213.

If state law imposes the same requirements at the state level as the FDCA imposes at the federal level, state law does not conflict with the FDCA. Quite the opposite: state law duplicates or parallels the FDCA. Although 21 U.S.C. § 337(a) bars private enforcement of the FDCA, neither that provision nor anything else in the FDCA bars States from enacting their own laws that duplicate, incorporate, or "parallel" FDCA requirements relating to prescription drugs. *Stengel*, 704 F.3d at 1230. This Court has held, for example, that state laws may "borrow" FDCA provisions, *McClellan*, 776 F.3d at 1040, and "provid[e] a damages remedy for claims premised on a violation of FDA regulations," *Stengel*, 704 F.3d at 1230 (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008)). The FDCA does not, in other words, preempt "claims under state law based on a . . . violation of federal law." *Id.* To the contrary, state laws that are "substantively identical" to the FDCA properly "parallel[] the

FDCA's prohibitions on marketing unapproved new drugs." U.S. *Athena* Br. 9.

That States remain free to enact their own laws in the fields of health, safety, and competition regulation so long as those laws do not conflict with the FDCA should not be a controversial proposition. For States to have been stripped of that authority, section 337(a) would have to bar not only private enforcement of the FDCA, but also prohibit the States from regulating in this field. *See Arizona*, 567 U.S. at 401 ("Field preemption reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards."). But section 337(a) does not say that, and not even Fagron is willing to say out loud that the FDCA occupies the field and ousts the States from health, safety, and competition regulation.

B. Hope's enforcement of state drug-approval laws does not require proof of any FDCA violation.

Since there is no express preemption provision relating to prescription drugs and field preemption is as much a non-starter as conflict preemption *sans* conflict, what kind of "preemption" is Fagron arguing? To avoid the well-established point that "parallel" state laws do not conflict with the FDCA, Fagron asserts—again and again, like a

comforting mantra—that Hope's claims required Hope to prove that Fagron violated the FDCA in addition to violating state law. *E.g.*, Br. 1, 4, 10, 18, 26–27. If that were true, according to Fagron, it would show Hope is really just enforcing the FDCA, contrary to section 337(a). But Fagron's mantra is not true.

As the district court recognized, Hope did not sue Fagron for violating the FDCA. 1-ER-123–25. Hope sued Fagron under *state* consumer-protection laws for violating *state* laws that prohibit the sale of unapproved drugs. 1-ER-77–83. Fagron does not dispute that the Five States prohibit, *as a matter of state law*, the in-state sale of drugs that have not received premarket approval from FDA or a state agency. *Id.* And Fagron does not dispute that the Five States, *as a matter of state law*, permit private parties to sue for violations of their drug-approval laws through their consumer-protection laws. *Id.*

These state drug-approval laws do not, as Fagron argues, require proof that a drug "violated the FDCA[]." Br. 27. Instead, as Fagron agreed below, they turn on the answer to a yes-or-no question: Has FDA granted premarket approval to the defendant's drug under FDCA section 505? SER-35–43. That is a simple factual question—either FDA granted

approval or it didn't. And if it didn't, then state law prohibits the sale of that drug. It is undisputed that Fagron's sodium thiosulfate drug has *not* received premarket approval from FDA. The Five States' drug-approval laws thus prohibit the sale of that drug.

For example, California's Sherman Law provides that "[n]o person shall sell, deliver, or give away any new drug" in California unless (1) "a new drug application has been approved for it . . . under [FDCA] Section 505" or (2) California "has approved a new drug . . . application for that new drug." Cal. Health & Safety Code § 111550(a)–(b). A Sherman Law claim thus turns only on the lack of premarket approval—not the violation of any FDCA requirement. The same is true of other state drug-approval laws.[5]

[5] *E.g.*, Tenn. Code § 53-1-110(a) ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA]."); S.C. Code § 39-23-70(a)–(b) ("No person shall introduce or deliver for introduction into intrastate commerce any new drug unless" South Carolina has approved the drug or "an application with respect thereto has been approved . . . under Section 505 of the [FDCA]"); Conn. Gen. Stat. § 21a-110(a) ("No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless . . . an application with respect thereto has been approved under Section [505] of the [FDCA] . . . ."). Although Florida also allows the sale of drugs that are "otherwise permitted by the Secretary of the United States Department of Health

To show a violation of these state laws, therefore, Hope needed to establish only the undisputed fact that Fagron has not received premarket approval for its drug under section 505 or state law. The state laws Hope sued under do not *also* require the plaintiff to prove that the defendant's drug was *not exempt* from premarket approval under federal law because (for example) it satisfies the FDCA's requirements for compounded drugs. Fagron even admits that the FDCA's exemption from premarket approval for compounded drugs is "not incorporated into the states' laws." Br. 30.

For that reason, Hope's theory of liability—which the district court adopted—requires no "mental acrobatics." Br. 11. Hope did not argue, as Fagron says, that Fagron's drug is "unapproved" because it is "not exempt from the FDCA's pre-market approval requirement." *Id.* Hope argued that Fagron's drug is unapproved *because it is unapproved*. If Fagron's drug were *exempt* from premarket approval, it still would not have *received* premarket approval—and so would still be "unapproved" under

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and Human Services," Fla. Stat. § 499.023, Fagron has never cited or relied on that provision. *See, e.g.*, SER-36. That is likely because it has never received permission from the HHS Secretary through any process, under section 505 or otherwise. *Cf., e.g.,* 21 U.S.C. § 360bbb-3 (providing for "emergency use" authorization).

the Five States' drug-approval laws. Whether Fagron's drug was "exempted from FDA pre-market approval," Br. 28–29, is irrelevant under the plain terms of the state laws that Hope sued under.

It is thus both wrong and incoherent for Fagron to claim the district court could not "find that [its] drug was unapproved under various state laws" without first "determin[ing] whether Fagron complied with the FDCA." Br. 18 (emphasis omitted). Fagron concedes its drug is unapproved. SER-32 ¶ 5. If it had "complied with the FDCA," Br. 18 (emphasis omitted), its drug might have been *exempt* from premarket approval under section 505—but, by definition, a drug cannot be *both* exempt from approval *and* approved. So the district court did not have to consider anything about the FDCA to find (in the second paragraph of its order) that Fagron has "not received FDA approval for [its] sodium thiosulfate drugs." 1-ER-53 ¶ 2. Nor did the district court have to consider the FDCA to find that Fagron "violated the Sherman Law" because it "sold in California [its] sodium thiosulfate drug, which has neither been approved by the FDA 'under [FDCA] Section 505,' nor by

California." 1-ER-77 ¶ 25. The same goes for the other States' drug-approval laws. 1-ER-78–83 ¶¶ 32, 38, 44, 51.[6]

To be sure, a defendant may—as Fagron did—choose to assert the FDCA's compounding exemption *as a defense* to a state-law lack-of-approval claim, arguing the Supremacy Clause requires States to allow the sale of compounded drugs that comply with the FDCA. *See* Br. 30. In response, the plaintiff may—as Hope did—show that the defendant's drug is not exempt from premarket approval under the FDCA's compounding provisions. But that does not mean Hope's state-law claims required proof of an FDCA violation. Hope addressed the FDCA's requirements only to respond to Fagron's defense, not as an element of its claims. *See Perry v. Merit Sys. Prot. Bd.*, 137 S. Ct. 1975, 1986 n.9 (2017) (plaintiffs need not "anticipate and negate" affirmative defenses). And while Fagron wanted this case to be about whether the Supremacy Clause requires States to allow the sale of unapproved drugs that comply with the FDCA's compounding provisions, the district court found—and Fagron does

[6] For the same reason, it is not true that "Hope's claims would not exist" if "the FDCA did not exist." Br. 26. State drug-approval laws prohibit the sale of unapproved drugs; all that would change if the FDCA suddenly disappeared is that section 505 wouldn't provide a means to get the required approval. Approval would have to come from state law.

not dispute—that its drug does *not* comply with the FDCA's compounding provisions. Because the factual premise of Fagron's defense was incorrect, that legal question is not presented here; instead, Fagron's argument on appeal is that federal law preempts Hope's claims *even though Fagron violates federal and state law alike*.[7]

The references to the FDCA's compounding provisions in Hope's complaint do not show that proving a violation of the FDCA was an element of Hope's claims. Br. 28. The complaint alleged Fagron violates the Five States' drug-approval laws by "selling[] and distributing unapproved new drugs." 3-ER-635 ¶ 23. The complaint described those state laws as prohibiting the sale of a drug "unless an application approved by FDA under section 505 of the FDCA is in effect for the drug." 3-ER-638 ¶ 45. A compounded drug does not receive approval "under section 505 of the FDCA." *Id.* Hope thus alleged Fagron violates the Five

[7] Fagron's effort to distinguish the Federal Circuit's decision in *Athena* relies on this same irrelevant legal argument. Fagron argues the FDCA preempts state drug-approval laws *because* they "[r]equir[e] pre-market approval . . . under state law" even when a drug is exempt from premarket approval under the FDCA. Br. 30 (emphasis omitted). Again, whether state law would be preempted *if* Fagron's unapproved drug were exempt from premarket approval under the FDCA's compounding provisions is beside the point given the district court's unchallenged finding that Fagron's drug is *not* exempt.

States' drug-approval laws "because [it] ha[s] not obtained the approval of FDA (or any other relevant regulatory authority) to introduce [its] compounded sodium thiosulfate drugs." 3-ER-640 ¶ 55. Moreover, the parties' final proposed pretrial order was explicit that Hope's "claims are based solely on [Fagron's] sale of drugs that have not received premarket approval." SER-44.

The complaint's references to the FDCA's compounding provisions, rather than establishing elements of Hope's claims, anticipate and rebut Fagron's *defense*.[8] So while it is true that Hope alleged—and the district court ultimately found—that Fagron's drug is not "exempted from FDA approval," that doesn't mean the "FDCA's requirements" were "an element of its claim." Br. 27–28. Fagron's "defense," *id.*, was that its drug *is* exempt from premarket approval. Hope could have argued that was no defense as a matter of law—in other words, that States may prohibit the sale of unapproved drugs even if they comply with the FDCA's

[8] *See, e.g.*, 3-ER-630 ¶ 1 ("Defendants purport to *avoid* drug-approval requirements by falsely presenting their products as lawfully 'compounded'" (emphasis added)); 3-ER-634 ¶ 21 ("Defendants falsely claim to be engaged in compounding and thus to be *exempt* from state . . . approval requirements." (emphasis added)); 3-ER-640 ¶ 58 ("Defendants purport to *avoid* the . . . pre-market approval requirement by relying on [compounding]" (emphasis added)).

compounding provisions. But because it was clear that Fagron's drug did not comply with the FDCA, Hope opted to indulge Fagron's legal premise and show that its factual premise was false. Regardless, by alleging and submitting evidence that Fagron's drug is not exempt, Hope was simply responding to Fagron's defense. Hope's *claims* were still based entirely on the undisputed fact that Fagron's drug has not received premarket approval from FDA or any State. *E.g.*, 3-ER-652–56 ¶¶ 101, 112, 120, 126.

Hope consistently advanced its claims in these terms. From the beginning of the case to the end, Hope maintained that it "need not prove [Fagron's] noncompliance with Sections 503A and 503B to show a violation of" state drug-approval laws. SER-17 ¶ 21, SER-20 ¶ 33, SER-21 ¶ 39, SER-23 ¶ 47.[9] Fagron even recognized this point before trial, describing Hope's "position" as being "that any sales of drugs not approved by the FDA violate[] the various state [drug-approval] laws." SER-29. Fagron admitted that, under Hope's argument, a compounded drug would not qualify as "approved by the FDA," irrespective of "the FDA regulatory scheme for compounding drugs." *Id.*

[9] *Accord, e.g.*, 2-ER-191; 3-ER-652–56 ¶¶ 101, 112, 120, 126; SER-5 n.1, 8 n.3, 11, 44, 62–65, 67–68, 71–72, 75, 78–79, 81, 84–85, 88–89, 92–96, 98.

For all these reasons, Hope's claims, under the terms of the state statutes that Hope invoked and as Hope litigated them, did not require it to prove that Fagron violated the FDCA as an element of its claims.

C. *Nexus* did not hold that state-law claims like Hope's involve improper private enforcement of the FDCA.

Fagron argues *Nexus* rejected claims like Hope's, but that is an overreading of *Nexus* and a misrepresentation of Hope's claims. There, the plaintiff's claims required proof that the defendant's drug *both* lacked FDA approval *and* violated the FDCA's requirements for compounded drugs. *Nexus*, 48 F.4th at 1044. Therefore, "a necessary element of [the plaintiff's] claim [was] the alleged violation of the FDCA." *Id.* at 1048.

Hope's claims are different. While *Nexus* treated a violation of the FDCA's compounding requirements as being an element of the plaintiff's claims, that is not true here. Rather, as explained above, Hope made clear that it sought only to enforce *state-law* requirements that Fagron receive premarket approval for its drug. And those statutes require premarket approval specifically *under section 505*—by their plain text, they do not require a plaintiff to prove that a defendant's unapproved drugs are not exempt from premarket approval. *Supra* at 38–40. To nonetheless extend

Nexus to Hope's claims would require a demonstrably incorrect interpretation of state drug-approval laws.[10]

Fagron's overbroad interpretation of *Nexus* also conflicts with Supreme Court precedent. The Supreme Court has long recognized that States may pass statutes prohibiting certain in-state conduct without federal approval. *E.g.*, *California v. Zook*, 336 U.S. 725, 726–28 & n.1 (1949) (upholding California statute prohibiting motor carriers from selling transportation without a federal or California permit); *see also Gilbert v. Minnesota*, 254 U.S. 325, 331 (1920); *Asbell v. Kansas*, 209 U.S. 251, 256–58 (1908); *cf. Arizona*, 567 U.S. at 402 ("a State may make violation of federal law a crime," unless federal law occupies the field). When a "state statute makes federal law its own" in this way, there is "no possibility of [a] conflict" between state and federal law, and thus no preemption. *Zook*, 336 U.S. at 735.

[10] To argue otherwise, Fagron asks this Court to rely on the complaints in the *Nexus* cases. Br. 24, 27. But this Court is bound by its *opinion* in *Nexus*, not by the contents of the parties' filings in the district court. *See Daimler AG v. Bauman*, 571 U.S. 117, 130 n.8 (2014) (rejecting interpretation of precedential "opinion" based on "the trial court record" in that case). The complaints Fagron submits are irrelevant to whether the Court's *Nexus* precedent covers Hope's claims.

The United States has taken the same position. In a Supreme Court amicus brief, the Solicitor General explained "that the FDCA does not impliedly preempt [a] private civil action . . . to enforce state drug pre-market approval requirements that are substantively identical to those imposed by the FDCA." U.S. *Athena* Br. 8.[11] States may "authoriz[e] private suits to enjoin the intrastate distribution, sale, and marketing of an unapproved drug" because the FDCA does not preempt state laws that "directly incorporate[] the federal new-drug application regulations." *Id.* at 9, 17. The FDCA's standing provision, after all, says only that actions to enforce *the FDCA* must be brought by the United States; it does not say that States are forbidden from enacting their own laws that parallel, rather than conflict with, the FDCA. Such state laws fall "within the State's historic purview to regulate health and safety, as well as to protect against unfair competition," a "role" the FDCA "preserves . . . for the States." *Id.* at 17 (cleaned up).

[11] *Nexus* disagreed with the Federal Circuit's decision in *Athena*, 48 F.4th at 1049–50, but (for the reasons already given) that is best understood as a rejection of the proposition that *Athena* allowed the *Nexus* plaintiff to assert an FDCA violation as an element of its state-law claims. *Nexus* did not address the Solicitor General's more general account of FDCA preemption.

Finally, Fagron's reading of *Nexus* conflicts with the California Supreme Court's decision in the *Farm Raised Salmon Cases*. There, the California Supreme Court held that the FDCA's standing provision did not preempt a private lawsuit to enforce the Sherman Law's food-labeling provisions, which copy and incorporate the FDCA's food-labeling requirements. 175 P.3d at 1175–76, 1181–84. "That the Sherman Law imposes obligations identical to those imposed by the FDCA," the court explained, "does not substantively transform plaintiffs' action into one seeking to enforce federal law." *Id.* at 1181. The same is true for claims under the Sherman Law's—and other state laws'—drug-approval provisions.

The United States, as in *Athena*, endorsed this reasoning in the Supreme Court. It explained: "Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself. . . . [E]ven when state-law claims are predicated on violations of the FDCA, they remain state-law claims." U.S. *Albertson's* Br. 12–13. The United States thus rejected the exact theory of FDCA preemption that Fagron erroneously reads *Nexus* to adopt. It would be anomalous to hold—in the name of protecting FDA's authority—that section 337(a) bars States from enacting laws that

parallel or incorporate the FDCA when the United States has twice told the Supreme Court that States retain that authority. *See Williamson v. Mazda Motor of Am., Inc.*, 562 U.S. 323, 336 (2011) (rejecting obstacle-preemption argument where the government did not view state law as an obstacle, as the relevant federal agency "is 'uniquely qualified' to comprehend the likely impact of state requirements").

II. Hope's claims do not conflict with FDA's authority.

Fagron also argues, again based on *Nexus*, that Hope's claims conflict with FDA's authority to interpret and enforce the FDCA. Here too, Fagron's argument overreads *Nexus* and conflicts with governing law.

A. State drug-approval laws generally do not conflict with FDA's authority.

The essential requirement for conflict preemption is, of course, a conflict between state and federal law. This Court's precedent makes clear that conflicts are not lightly found, especially in areas of traditional state authority. *In re Volkswagen*, 959 F.3d at 1212–13. And no such conflict exists here.

As a general matter, allowing States to prohibit the in-state sale of unapproved drugs does not interfere with or disrupt FDA's authority. The mere fact that States and the FDCA both prohibit the sale of unapproved

drugs does not show a conflict; this "Court does not infer Congress intended to preempt state enactments merely because they overlap with a federal act." *Id.* at 1213. To the contrary, there is "no possibility of [a] conflict" when a "state statute makes federal law its own." *Zook*, 336 U.S. at 735. As the United States has explained, state laws that "directly incorporate[] the federal new-drug application regulations" will rarely conflict with "the FDCA's prohibitions on marketing unapproved new drugs." U.S. *Athena* Br. 9.

To the extent a parallel state-law claim could interfere with FDA's regulatory authority when it relates to a provision FDA is currently interpreting or under other unusual circumstances, the correct response would be to stay the action under the "primary jurisdiction" doctrine. *E.g.*, *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760–62 (9th Cir. 2015). The factors Fagron claims support conflict preemption—FDA's "regulatory authority," "expertise," and supposed desire for "uniformity in administration"—can "warrant[] invocation of primary jurisdiction" in a particular case. *Id.* at 760 (cleaned up); *see* Br. 31–32. When they do, a court may "stay proceedings rather than dismissing them," so FDA can "provide expert advice that would be useful to the court in considering

th[e] lawsuit." *Astiana*, 783 F.3d at 762. But in no event does FDA's enforcement authority support the sweeping preemption for which Fagron advocates, which would bar every claim under every state drug-approval statute, even in the absence of any actual conflict with federal law—in other words, field preemption. *Id.* at 761–62; *Azurity*, 45 F.4th at 500.

Fagron's contrary argument cannot be squared with *Wyeth*. The defendant in *Wyeth*, like Fagron, argued that the plaintiff's state-law claims "interfere[d] with Congress's purpose to entrust an expert agency to . . . strike a balance between competing objectives." 555 U.S. at 573 (cleaned up). The Court rejected that argument because "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. To the contrary, "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 578.

Fagron relies on the same "untenable interpretation of congressional intent" that *Wyeth* rejected. *Id.* at 573. Nothing in the FDCA suggests that States are barred from enacting their own laws regarding drug safety and providing for their enforcement. *Id.* at 567. The

exact opposite is true: "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's [85]-year history." *Id.* at 574.

Nor does allowing States to prohibit the sale of unapproved drugs create a "perverse situation" by imposing civil liability "where the FDA had not found a violation." Br. 32. In this case specifically, the district court found that Fagron's unapproved drug is not exempt from premarket approval under the FDCA, and Fagron does not challenge that finding on appeal. Fagron cannot argue FDA might not find that it violated the FDCA when it no longer disputes that it *did* violate the FDCA. More generally, if Fagron means to suggest that where FDA has "not found a violation," that must mean FDA has found that there *is no* violation, the Supreme Court and the United States have explained the fallacy of such a suggestion. FDA "has limited resources to monitor the . . . drugs on the market," *Wyeth*, 555 U.S. at 578, so "[n]o conflict with a supposed FDA position . . . can be inferred from the absence of FDA enforcement," U.S. *Athena* Br. 10; *see also Azurity*, 45 F.4th at 502 ("FDA has discretion to enforce the law, but the lack of enforcement does not make [a] defendant's action's legal." (cleaned up)); *Farm Raised Salmon*, 175 P.3d at 1184

("[W]hile allowing private remedies based on violations of state laws identical to the FDCA may arguably result in actions that the FDA itself might not have pursued, Congress appears to have made a conscious choice not to preclude such actions.").[12]

B. *Nexus* did not hold that state-law claims like Hope's conflict with FDA's authority.

Nexus does not support Fagron's argument that Hope's claims conflict with FDA's authority, because its finding of a conflict depended on unique features of the plaintiff's claims that do not exist here. As explained, a "necessary element" of the *Nexus* plaintiff's state-law claims was that the defendant violated the FDCA's "essentially a copy" provision for sterile-to-sterile compounding. 48 F.4th at 1048. But FDA declared it was in the process of revising its guidance for the exact provision at issue, which applied when "outsourcing facilities 'compound drug products using FDA-approved drug products—*rather than bulk drug substances*—as a starting point.'" *Id.* at 1044 (emphasis added). In that context, this

[12] Fagron presumably does not mean to suggest that FDA has found that its unapproved drug *is* exempt from premarket approval, as that would be false. Far from making such a finding, FDA *rejected* Fagron's argument that there is a clinical need for 503B facilities to use bulk sodium thiosulfate to make unapproved drugs like Fagron's. 87 Fed. Reg. at 4249–50 (2-ER-216–17); Br. 19, 31.

Court held the plaintiff's claims could interfere with FDA's authority to interpret the sterile-to-sterile "essentially a copy" provision. *Id.* at 1050.

Hope's claims present no similar risk of conflict. Unlike in *Nexus*, Hope's claims did not require it to prove a violation of any FDCA requirement. Hope's claims turned only on whether FDA approved Fagron's drug under section 505, which is a simple question of undisputed historical fact. SER-32 ¶ 5. Recognizing that fact did not require the court to interpret any provision of the FDCA, so it could not interfere with FDA's authority. *See Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) (holding a "determination of whether [a] product has received FDA approval" does not "require[] the FDA's scientific expertise"); *Azurity*, 45 F.4th at 501 (same).

That aside, the *Nexus* appeal arose from a motion to dismiss, when the district court would still need to decide in the future whether the defendant had violated the FDCA—and the defendant disputed that claim. This case, in contrast, comes to the Court after a trial, where the district court found Fagron's unapproved drug was not exempt from premarket approval under federal law—and Fagron does not challenge that finding. Fagron cannot claim the district court's interpretation of the

FDCA could conflict with FDA's interpretation when Fagron cannot even bring itself to argue that the district court's interpretation was erroneous.

The FDCA, moreover, contains multiple requirements for compounders, and Fagron's drugs are not exempt from premarket approval for reasons that did not exist in *Nexus*. Nothing in *Nexus* suggests that every FDCA requirement presents the same risk of an interpretive conflict, so its holding based on the FDCA's "essentially a copy" provision for sterile-to-sterile compounding cannot automatically be extended to other provisions that were not at issue.

In particular, while Fagron focuses on the FDCA's "essentially a copy" provisions, its unapproved drug would not be exempt from premarket approval under section 503B even if it satisfied the "essentially a copy" provision for bulk-drug-substance compounding. Fagron's drug cannot be exempt unless (1) Hope's Sodium Thiosulfate Injection appears on FDA's drug shortage list or (2) sodium thiosulfate appears on FDA's 503B bulks list. 1-ER-19 ¶ 29; 21 U.S.C. § 353b(a)(2)(A). But it is undisputed that neither is true: Hope's Sodium Thiosulfate Injection has never appeared on FDA's drug shortage list, and FDA definitively decided to put sodium thiosulfate on the "no clinical need" list, not on the bulks list. 1-ER-38, 1-

ER-67 ¶ 57. As a result, Fagron cannot deny its drug is not exempt from premarket approval. Br. 19, 31; 1-ER-39.

That application of section 503B presents no possible conflict with FDA's authority. There are no "difficult issues of interpret[ation]," *Nexus*, 48 F.4th at 1050, because there is nothing to interpret—you just have to look at the lists. There is no risk of a court taking a different position than FDA, since the lists reflect decisions that FDA has already made. And there is no risk of "inconsistent determinations" or "state-by-state restriction[s] on compounding" because the lists "appl[y] across the board to all outsourcing facilities." Br. 31–32.

The First Circuit recently reached the same conclusion in a case under the Lanham Act. *Azurity*, 45 F.4th at 499–502. There, the plaintiff claimed the defendant violated the Lanham Act by representing that its compounded drug satisfied section 503B even though it contained a "bulk drug substance" that did not appear on the bulks list. *Id.* at 495 (cleaned up). The district court dismissed the plaintiff's claim, holding "the FDCA precluded" it because it "would require a court to interpret the meaning of section 503B in a way that would interfere with the FDA's authority to administer and enforce the FDCA." *Id.* at 484. The First Circuit reversed.

As relevant here, the First Circuit first rejected the defendant's argument based on the FDCA's standing provision, holding the plaintiff sought "to enforce the Lanham Act, not the FDCA or its regulations." *Id.* at 500 (quoting *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 117 (2014)). The court then held the plaintiff's claim was not "precluded because it depends on the meaning of a law that the FDA administers." *Id.* The "relevant portion of section 503B," the court held, "is clear: one of the statutory 'conditions' for 'outsourcing facilit[ies]' is that the 'facility . . . does not compound using bulk drug substances . . . unless' the substance appears on a [FDA] list." *Id.* at 501 (quoting 21 U.S.C. § 353b(a)(2)). So "the adjudication of [the plaintiff's] claim simply require[d] a court to ascertain whether a particular drug appears on either the [bulks list], or on the drug shortage list." *Id.* That presented no "conflict" with "FDA policy discretion." *Id.* at 502.

Here too, resolving Fagron's FDCA defense "simply requires a court to ascertain whether [sodium thiosulfate] appears on either the [bulks list], or on the drug shortage list." *Id.* at 501. *Nexus* did not address whether that inquiry would conflict with FDA's authority, and it plainly does not. *Id.* at 501–02.

The same is true for section 503B's "essentially a copy" provision for bulk-drug-substance compounding. Fagron obfuscates this point by suggesting that *Nexus* and this case involve the same "essentially a copy" provision. Br. 14, 18, 27. But, as explained, section 503B contains *two* "essentially a copy" provisions, which impose different requirements on sterile-to-sterile and bulk-drug-substance compounding. 21 U.S.C. § 353b(d)(2)(A), (d)(2)(B). *Nexus* involved only sterile-to-sterile compounding, 48 F.4th at 1044, while this case involves only bulk-drug-substance compounding, *Hope*, 2021 WL 5860886, at *1; SER-33 ¶ 13. The provision at issue here thus has different requirements and is subject to different FDA guidance than the provision at issue in *Nexus*—a distinction this Court drew in rejecting Fagron's earlier appeal. *Hope*, 2021 WL 5860886, at *1; SER-33 ¶ 13. So whether Hope's claims conflict with FDA's authority to interpret the "essentially a copy" provision for bulk-drug-substance compounding cannot be resolved through Fagron's talismanic invocation of *Nexus*, where that provision was not relevant. Any such conflict must instead be found based on a comparison between Hope's specific claims and the specific provision at issue. *See Azurity*, 45 F.4th at 494 n.7 (holding "the preclusion analysis depends in large part

on the precise nature of the claim brought"). Absent such an actual, case-specific conflict, holding that the FDCA bars state-law claims would amount to holding that the FDCA occupies the field—an untenable notion that not even Fagron is willing to embrace.

And here, there is no conflict between Hope's claims and FDA's authority to interpret the "essentially a copy" provision for bulk-drug-substance compounding. In *Nexus*, FDA declared that the plaintiff's claims could conflict with its ongoing efforts to revise its guidance specifically for sterile-to-sterile compounding. *Nexus*, 48 F.4th at 1044. FDA also explained, however, that it "has not changed and is not planning to change its regulations concerning [bulk-drug-substance compounding] facilities" like Fagron's. *Hope*, 2021 WL 5860886, at *1; *see* 2-ER-271. So while this Court worried in *Nexus* that the plaintiff's claim could conflict with FDA's ongoing revisions to its guidance for sterile-to-sterile compounding, 48 F.4th at 1050, there is no similar concern here where the relevant guidance is final, *Hope*, 2021 WL 5860886, at *1.

Indeed, the district court in this case rejected Fagron's claim to comply with section 503B by following FDA's guidance for bulk drug compounding to the letter. *See* 1-ER-62–63 ¶¶ 30–31. The "essentially a

copy" provision for such compounding is thus at no risk of "inconsistent determinations." Br. 31. And Fagron does not identify any ambiguity in how the provision applies to its drug. Fagron admits sodium thiosulfate is a "component" of both its unapproved drug and Fagron's "approved drug." 21 U.S.C. § 353b(d)(2); SER-33 ¶¶ 10–11. The only disputed question at trial was whether Fagron sold its drug with the required "clinical difference" statements. 1-ER-74–76. The district court found that it did not, *id.*, and Fagron does not challenge that finding on appeal. That case-specific factual "question of documentation of [clinical] differences . . . is not a question of rulemaking authority" that could conflict with FDA's interpretation of the FDCA. 1-ER-125.

III. The Court should consider inviting the United States to express its views on this case.

If this Court has any doubts about how its precedents—including *Stengel* and *McClellan* as well as *Nexus*—apply to this case, it should invite the United States to submit its views on the question. The United States has argued that the FDCA does not preempt claims similar to Hope's on at least two occasions, in *Athena* and *Farm Raised Salmon*, and Fagron's interpretation of *Nexus* conflicts with the United States' position in those cases. *See supra* at 48–50.

As noted above, it would be highly unusual to find that state-law claims pose an obstacle to a federal agency's regulatory scheme where the federal government denies there is a problem. *Williamson*, 562 U.S. at 336. Even Fagron recognizes this point, arguing FDA has "a unique understanding of the [FDCA] and "an attendant ability to make informed determinations" on whether state laws are a threat to Congress's objectives. Br. 22 (quoting *Wyeth*, 555 U.S. at 577). It is likely, therefore, that the Court would benefit from the United States' input on Fagron's arguments. *See Cooper v. Tokyo Elec. Power Co. Holdings, Inc.*, 960 F.3d 549, 567–68 (9th Cir. 2020) (discussing Court's invitation of brief from United States); *Ministry of Def. & Support for Armed Forces of Islamic Rep. of Iran v. Cubic Def. Sys., Inc.*, 665 F.3d 1091, 1095 (9th Cir. 2011) (same); *Eid v. Alaska Airlines, Inc.*, 621 F.3d 858, 879 n.9 (9th Cir. 2010) (Otero, J., concurring) (same).

IV. If Fagron's interpretation of *Nexus* is correct, then *Nexus* should be overruled by the en banc Court.

For all the reasons discussed above, *Nexus* does not support Fagron's argument that the FDCA preempts Hope's claims. If the Court nonetheless concludes *Nexus* controls this case and requires reversal, then *Nexus* would represent a radical and badly mistaken departure from

Supreme Court precedent, en banc and panel opinions from this Court, decisions from other federal courts of appeals and the California Supreme Court, and the United States' views on FDCA preemption. Those conflicts would warrant en banc review to overrule *Nexus*.

First, if *Nexus* required preemption of any private claim under a state drug-approval statute, then *Nexus*—beyond endorsing an erroneous reading of state law, *supra* at 46–47—would conflict with Supreme Court cases holding that federal preemption does not bar States from conditioning in-state conduct on compliance with federal law. *E.g.*, *Zook*, 336 U.S. at 735. *Nexus* would also conflict with this Court's decisions in *Stengel* and *McClellan*, which expressly held that States may incorporate the FDCA's requirements into state-law causes of action without violating the FDCA's standing provision. *Stengel*, 704 F.3d at 1230; *McClellan*, 776 F.3d at 1040–41.

Stengel and *McClellan* also rejected the broad interpretation of *Buckman* that Fagron reads *Nexus* to endorse. Br. 31–32. *Buckman* involved a claim for "fraud against federal agencies," which is "hardly a field which the States have traditionally occupied." *Nexus*, 48 F.4th at 1046 (quoting *Buckman*, 531 U.S. at 347); *see GEO Grp., Inc. v. Newsom*,

50 F.4th 745, 761–62 (9th Cir. 2022) (en banc). *Stengel* and *McClellan* thus properly limited *Buckman* to fraud-on-FDA claims. *Stengel*, 704 F.3d at 1230, 1233; *McClellan*, 776 F.3d at 1040; *accord Wyeth*, 555 U.S. at 565 n.3; U.S. *Athena* Br. 12–17. Similarly, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), and *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013)—on which *Nexus* also relied—found preemption because the plaintiff alleged fraud related to FDA approval. *Nexus*, 48 F.4th at 1048–49.[13] In contrast, non-fraud claims like Hope's "have little to do with direct regulatory interaction with the FDA" and thus do not "usurp the exclusive federal enforcement power over the [FDCA]." *McClellan*, 776 F.3d at 1040–41; *accord Stengel*, 704 F.3d at 1233.

Nexus distinguished *Stengel* on the ground that it involved a state *tort* claim while the *Nexus* plaintiff sued under state *statutes*, 48 F.4th at 1048, but neither *Stengel* nor the FDCA supports such a distinction. *Cf. Riegel*, 552 U.S. at 325 (holding FDCA medical-device requirements equally preempt "common-law duties" and "state statute[s]"). *Nexus* did

[13] In addition, *PhotoMedex* addressed a Lanham Act claim, and its treatment of that claim was overruled by the Supreme Court in *POM Wonderful*. *See Azurity*, 45 F.4th at 488–89, 502 n.11; *Surgical Instr. Serv. Co. v. Intuitive Surgical, Inc.*, 571 F. Supp. 3d 1133, 1142–43 (N.D. Cal. 2021).

not explain why a statutory "restraint on the distribution of unapproved drugs poses a vastly greater threat to national uniformity than failure-to-warn litigation and other traditional state tort suits." U.S. *Athena* Br. 14–15 (cleaned up). Nor did it explain why Congress would have wanted to eliminate States' historic authority to regulate drug safety and fair competition by statute but not through the common law. After all, a "state statute" can "make[] federal law its own" no less than state common law. *Zook*, 336 U.S. at 735. If anything, a tort/statute distinction is backwards: it "would grant greater power . . . to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." *Lohr*, 518 U.S. at 504 (Breyer, J., concurring).

In addition to conflicting with *Stengel* and *McClellan*, Fagron's interpretation of *Nexus* would create a circuit split with the Federal Circuit's decision in *Athena*, which held the FDCA's standing provision does not preempt the Sherman Law's drug-approval requirements. *Athena*, 738 F.3d at 1354–56. Indeed, *Nexus* openly acknowledges its disagreement with *Athena*. 48 F.4th at 1049–50. Fagron argues *Athena* is distinguishable because the drug there was not exempt from premarket approval, Br. 29–30, but *neither is Fagron's drug*. The district

court found as much, and Fagron does not challenge that finding on appeal. So if *Nexus* applies here, it directly conflicts with *Athena*.[14]

Second, if *Nexus* held state drug-approval laws always conflict with FDA's authority to enforce the FDCA, that holding would conflict with this Court's recognition that preemption does not exist "merely because [state statutes] overlap with a federal act." *In re Volkswagen*, 959 F.3d at 1213. It would conflict with the Supreme Court's holding in *Wyeth* that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." 555 U.S. at 575; *accord Stengel*, 704 F.3d at 1230–31; U.S. *Athena* Br. 10. And it would conflict with the First Circuit's holding in *Azurity* that judicial interpretation of the FDCA's "bulk drug substance" provisions does not conflict with FDA authority. 45 F.4th at 501–02.

If *Nexus* required the Court to create these conflicts, they would have to be cured through en banc review. But *Nexus* does not require that result because it does not apply to Hope's claims. The consequences that would follow from adopting Fagron's contrary argument simply confirm the point.

[14] Fagron's interpretation of *Nexus* also conflicts with *Farm Raised Salmon* and the Solicitor General's amicus briefs in *Athena* and *Farm Raised Salmon*. *Supra* at 48–50.

V. Hope is entitled to fees and costs.

Fagron's argument that Hope should not receive attorney fees and costs falls with its preemption argument. Fagron concedes that because Hope prevailed below, it was entitled to costs under Rule 54(b) and to a mandatory award of fees under South Carolina law. Br. 33. Fagron argues only that Hope would no longer be entitled to fees or costs "[i]f th[e] Court reverses" the judgment based on Fagron's preemption argument. *Id.* Because Fagron's preemption argument is meritless, it provides no basis to reverse either the judgment or the award of fees and costs.

CONCLUSION

This Court should affirm the district court's judgment.

Respectfully submitted,

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February 21, 2023

STATEMENT REGARDING ORAL ARGUMENT

In light of the novelty and drastic implications of Fagron's preemption argument, Hope requests oral argument. Contrary to Fagron's statement, *Nexus* did not address "the same issue of law" or "virtually identical facts" as in this case, Br. 36, so the Court would benefit from argument on how its precedent—including *Stengel*, *McClellan*, and *Nexus*—applies to state-law claims like Hope's.

Date: February 21, 2023

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

Counsel for Appellee

STATEMENT OF RELATED CASES

Pursuant to Circuit Rule 28-2.6, I state that I am not aware of any related case pending in this Court.

Date: February 21, 2023

/s/ Jeffrey S. Bucholtz
Jeffrey S. Bucholtz

Counsel for Appellee

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32 and Circuit Rule 32-1, I certify that:

1. This document complies with the length limitation of Circuit Rule 32-1(a) because it contains 13,935 words, excluding the parts exempted by Fed. R. App. P. 32(f).

2. This document complies with the typeface and type-style requirements of Fed. R. App. P. 27(a)(5)–(6) because it has been prepared in a proportionally spaced typeface using Century Schoolbook size 14-point font with Microsoft Word.

Date: February 21, 2023

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